REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks and accompanying information, which place the application in condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-7, 9-24 and 32-56 were pending in this application. Claims 24 and 43-56 have been canceled. Support for the claim amendments is found throughout the specification as originally filed. The important aspects containing information on the individual claim elements will be addressed in Section III below. No new matter has been added.

The Examiner is thanked for withdrawing the obvious rejection of Kellogg in view of Kellogg.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. THE DOUBLE PATENTING REJECTIONS ARE OVERCOME

Claims 1-7, 9-24 and 32-56 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3, 5-20 and 29-37 of U.S. Patent No. 6,582,662 to Kellogg et al. in view of U.S. Patent 6,063,589 to Kellogg et al. In addition, claims 1-7, 9-23 are provisionally rejected under the judicially created doctrine of obviousness type double patenting as allegedly being unpatentable over claims 1-22 of copending Application No. 10/746,821 in view of U.S. Patent No. 6,063,589 to Kellogg et al. Finally, claims 37 and 38 stand rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-2 of U.S. Patent 6,709,869 to Mian et al. in view of U.S. Patent 6,063,589 to Kellogg et al.

If, upon agreement as to allowable subject matter, it is believed that there is still a double patenting issue, a Terminal Disclaimer as to U.S. Patent No. 6,582,662, U.S. Patent No.

6,709,869 and the copending Application No. 10/746,821 will be filed for the purposes of expediting prosecution.

Accordingly, Applicants request withdrawal of the double patenting rejection or that the rejection be held in abeyance.

III. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

All of the pending claims were rejected under 35 U.S.C. §102(b) as allegedly anticipated by European publication 0 608 006 to Abaxis, Inc. (hereinafter "Abaxis"). The Office Action alleges that Abaxis discloses analytical rotors which are microsystem platforms that use centripetal force to move microvolumes of fluids throughout the device. The Office Action also alleges that a bulk diluent reservoir described in Abaxis is equivalent to Applicants' claimed bulk diluent reservoir, while the diluent metering chamber is equivalent to Applicants' claimed reagent manifold. The Office Action further contends that the mixing chamber described in Abaxis is equivalent to the microfluidic mixing channels disclosed in the present invention. These rejections are respectfully traversed. The cited references do not anticipate the pending claims.

There are four essential elements of the claimed microsystems platform. The first of these elements is a multiplicity of microfluidics structures, discussed in detail below. The second element is a plurality of aliquotting manifolds which feed into the microfluidics structures. The third element is a plurality of bulk reagent reservoirs which are fluidly connected to the aliquotting manifolds. The forth element is a reagent overflow reservoir. The first two elements are not taught or suggested by the Abraxis reference. Moreover, the interplay between the various elements is not taught or suggested by Abraxis.

Based on comments made in the last Office Action, there appears to be some confusion in regards to how these various elements are interconnected and how they are distinct from Abraxis. Independent claim 1 has been amended for clarification purposes as to stress the key elements of the microsystems platform and how these elements are connected. Before addressing the Abraxis reference, however, the critical aspects of the claimed invention will be discussed.

The essential feature of the microsystems platform is the 'multiplicity of microfluidics structures', element (a) in claim 1. Three of these microfluidics structures are shown in **Figure 6**

of the specification as originally filed. **Figure 6** displays all of the components of the microfluidics structure, including those components in the reservoir (upper) layer and the microfluidics layer (lower) layer. The portion of one the microfluidics structure in the reservoir layer is detailed in **Figure 4D**. The important features in **Figure 4D** are the 'aliquotted reagent reservoirs' (**416** and **417**), the sample reservoir (**418**), and the detection reservoir (**420**).

Once the samples and reagents are aliquotted to their respective reservoirs, the samples must be mixed and transferred to the detection chamber. Such mixing and transferring is done in the mixing microchannels, which are embedded in the microfluidics layer of the claimed microsystems platform An example of one such mixing microchannel is displayed in **Figure 5B**. The microchannels in **Figure 5B** are directly connected to the reagent and reservoir layers. The force generated by rotating the platform enables the fluids to move from these reservoirs through the mixing microchannels, where the fluids are mixed to form a homogenous mixture. Once mixed, the fluids enter the detection chamber and the assay is completed. It is important to point out that these microfluidics structures are repeated a multiplicity of times on the microsystems platform, thus enabling the user to carry out numerous assays or reactions at once

Distributing the reagents on the microsystems platform prior to the large number of aliquotted reagent reservoirs on the periphery of the platform posed a considerable challenge. To achieve such distribution into the multiplicity of reagent reservoirs throughout the platform, Applicants devised a plurality of reagent aliquotting manifolds (element (d) in claim 1) which bring fluids from the 'bulk reagent reservoirs' to the 'aliquotted reagent reservoirs. Because the 'multiplicity of microfluidics structures' are located on the periphery of the microsystems platform, the aliquotting manifold was positioned radially across the surface of the platform. Rotation of the platform leads to fluid movement from the bulk reservoir to the aliquotting manifold. In the Examples described in the specification, there are two reagents mixed or reacted with one sample. As a result, there must be two aliquotting systems located on different dimensions of the platform. Thus, manifold **210 (Figure 2A)** is located on the upper half of the reservoir layer while manifold **409 (Figure 4B)** is on the lower half. The manifolds are described on page 23, lines 5-11 and lines 29-31, of the specification as originally filed.

The net effect of the reagent aliquotting manifold is that bulk regents can be simply added to a single bulk reagent reservoir (element (d) of claim 1) and be distributed evenly to a plethora of smaller reservoirs. However, the goal of the present invention is to mix a multiplicity

of different samples with the bulk reagents and thereby analyze many reactions at one time. To achieve this goal, Applicants introduced a multiplicity of entry holes on the top of the reservoir layer which can be accessed via a pipette. These holes are clearly displayed in **Figure 2A** of the specification. As described in the specification, "these ports have dimensions adapted to automated loading devices such as micropipettors." (Page 22, lines 28-30). Note that the samples are transferred to the sample reservoirs after being pipetted. Following rotation of the platform and distribution of the reagents into the aliquotted reagent reservoirs, the samples and reagents are mixed (or reacted) and than sent to the detector for analysis.

The interplay of the various elements on the claimed microsystems platform, particularly the multiplicity of microfluids structures and the aliquotting manifolds, allows the user to perform microanalytic and microsynthetic analysis in a simple, economical way where fluids are not needlessly wasted. More importantly, as stated in the final paragraph of page 20 of the specification, "the disc illustrates that identical assays may be made repeating assay structures around the disc at a given radius." Moreover, "it is estimated that that greater than 10,000 assays having a volume of 1-5 nL can be created in a circular platform having a 6 cm radius."

The Office Action equates the present invention which the rotor described in Abraxis. The Abraxis platform is inherently different than the microsystems platform of the present invention. The rejection apparently is based on the premise that the Abraxis platform has some elements in common with the presently claimed invention, such as a bulk reagent reservoir and an overflow reservoir. The Office Action alleges that Abraxis teaches a microsystems platform with all the same elements as the present invention. However, it is submitted the platform described in rotor lacks all of the essential elements claimed in the present invention that allow a chemist or biologist to carry out a multiplicity of assays on a single disc. Moreover, the means by which the various elements in the present invention are functionally interconnected is not present in Abraxis.

Abraxis does not teach or suggest a rotor with a 'multiplicity of microfluidics structures', the essential element of the present invention. As described above, the fact that these 'microfluidics structures' can be repeatedly positioned throughout the periphery of the disc enables the performance of multiple assays at once. The Office Action does not show an element on the Abraxis platform equivalent to the 'multiplicity of microfluidics structures.' However, the Office Action indicates that the 'mixing microchannel', a component of each

microfluidics structure, is equivalent to the separation chamber on the Abraxis platform. Thus, the Office Action concludes that "there is no patentable difference between a chamber and a channel, where Applicants have not stated any reason why a channel would give unexpected results over a chamber."

In this regard, it is respectfully pointed out that the Examiner is missing the whole point of the present invention. The purpose of the 'microfluidics structures', which include the mixing microchannels, is to allow the performance of a multitude of reactions at once. The separation chamber in Abraxis, on the other hand, only allows for the performance of a single reaction to be carried out. However, the Office Action is equating a bulk reagent chamber, where a single reaction can be carried out, with a multitude of reagent chambers, where a plethora of different reactions are carried out in mixing microchannels. Thus, the 'multiplicity of microfluidics structures' and the mixing microchannels are patentably distinct from the bulk chamber described in Abraxis. Moreover, the reason why Applicants require these repeating elements is repeated throughout the specification of the patent as originally filed.

With respect to the reagent aliquotting manifolds, it is difficult to understand the Examiner's position. The independent claims clearly indicate that the "aliquotting manifold(s) is fluidly connected to the plurality of aliquotted reagent reservoirs." Because the plurality of aliquotting reagent reservoirs is absent in Abraxis, Abraxis would have no need for such an aliquotting manifold. Yet, the Office Action apparently equates the aliquotting manifold with a metering chamber that connects to an overflow chamber. The function and design of the metering chamber in Abraxis is completely distinct from the claimed aliquotting manifold of the present invention. The metering chamber in Abraxis has two outlets, one which feeds into a separation chamber and one that feeds into an overflow chamber. Contrast this with the aliquotting manifolds of the present invention which extend radially across the disc and feed into a multiplicity of aliquotted reagent reservoirs. As such, Abraxis would not be able to perform a multiplicity of different reactions as in the present invention but will be restricted to a single bulk reaction taking place in the separation chamber. The fact that Abraxis uses small volumes of liquids has no relevance.

In short, Abraxis does not teach or suggest the important elements of the present invention. Because these essential element is missing in Abraxis, the 102(b) rejection should be removed. Even if some of the elements in the Abraxis platform are present in the presently

claimed microsystems platform, the means by which these elements are functionally connected are significantly different and as a result, the utility of the two platforms are completely different as well.

Consequently, reconsideration and withdrawal of the Section 102 rejections are earnestly requested.

REQUEST FOR AN INTERVIEW

If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested and the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the remarks, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,
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